Declaration, Power Of Attorney and Petition

Page 1 of 3

WE (I) the undersigned inventor(s), hereby declare(s) that:

My residence, post office address and citizenship are as stated below next to my name,

We (I) believe that we are (I am) the original, first, and joint (sole) invertor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled

MURINE α(1,3) FUCOSYLTRANSFERASE FUC-TVII, DNA ENCODING THE SAME,
METHOD FOR PREPARING THE SAME, ANTIBODIES RECOGNIZING THE SAME,
IMMUNOASSAYS FOR DETECTING THE SAME, PLASMIDS CONTAINING SUCH DNA,
AND CELLS CONTAINING SUCH A PLASMID
the specification of which

	is attached hereto.	
⊠ĸ	was filed on MARCH 8, 1996	_ as
	Application Serial No. 08/613,098	
	and amended on	·
	was filed as PCT international application	
Nu	mber	
on	· · · · · · · · · · · · · · · · · · ·	
and	d was amended under PCT Article 19	
on	(if applica	ıble).

- We (I) hereby state that we (I) have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.
- We (I) acknowledge the duty to disclose information known to be material to the patentability of this application as defined in Section 1.56 of Title 37 Code of Federal Regulations.
- We (I) hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed. Prior Foreign Application(s)

Application No.	Country	Day/Month/Year	Priority Claimed	
 			□ Yes	□ No
 4.7	<u>·</u>		□ Yes	□No
 			□ Yes	□ No
 			□ Yes	□ No



Page 2 of 3 Declaration

We (I) hereby claim the benefit under	Title 35, United States	Code, § 119(e) of any	United States provisional
application(s) listed below.			

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

ea in in	CT International application designation of the claims of this application is the manner provided by the first	ating the United States, listed belos not disclosed in the prior United st paragraph of 35 U.S.C. § 112 ntability as defined in 37 CFR § 1.	States application(s), or § 365(c) of any w and, insofar as the subject matter of States or PCT International application, I acknowledge the duty to disclose 56 which became available between the I filing date of this application.
	Application Serial No.	Filing Date	Status (pending, patented, abandoned)
1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1			· ·
NSOPERRN 32 RWRRHHMA mkuti 2	Jumber 24,913; C. Irvin McClelland, 5,599; Arthur I. Neustadt, Registration, Hamilton, Registration Number ous, Registration Number 29,099; egistration Number 29,004; Will egistration Number 30,073; Robert Jumber 31,451; William B. Walker, 12,171; Stephen G. Baxter, Registrationer W. Hahl, Registration Number 32, egistration Number 34,651; William application and to transact all but at all correspondence regarding this AIER & NEUSTADT, P.C., who arlington, Virginia 22202. We (I) declare that all statements and on information and belief are Inowledge that willful false statements nowledge that willful false statements	d, Registration Number 21,124; Gon Number 24,854; Richard D. Ke 28,421; Eckhard H. Kuesters, Re Charles L. Gholz, Registration Niam E. Beaumont, Registration F. Gnuse, Registration Number 22,498; Time tion Number 32,884; Martin M. ber 33,893; Richard L. Treanor, F. 829; John T. Goolkasian, Registration J. Healey, Registration Numy) attorneys, with full powers of susiness in the Patent Office connects application be sent to the firm of the see Post Office Address is: Fourthmade herein of our (my) own known believed to be true; and further that and the like so made are punished united States Code and that such patent issuing thereon.	24,618; Marvin J. Spivak, Registration fregory J. Maier, Registration Number 21,757; James egistration Number 28,870; Robert T. Iumber 26,395; Vincent J. Sunderdick, Number 30,996; Steven B. Kelber, 7,295; Jean-Paul Lavalleye, Registration Number Zoltick, Registration Number 35,745; Registration Number 36,379; Steven P. Ition Number 26,142; Marc R. Labgold, Inber 36,160; and Richard L. Chinn, Inbstitution and revocation, to prosecute the ded therewith; and we (I) hereby request of OBLON, SPIVAK, McCLELLAND, Floor, 1755 Jefferson Davis Highway, Inswed the statements were made with the mable by fine or imprisonment, or both, a willful false statements may jeopardize 1423 Natalie Lane, #79

Shunji NATSUKA	Residence: 1423 Natalie Lane, #79
NAME OF FIRST SOLE INVENTOR	
5-12/3/	Citizen of:JAPAN
Signature of Inventor	Post Office Address: Same as above
Date May 14 1886	
Date .//	

Kevin M. GERSTEN	Residence: 1826 N. 57th Street
NAME OF SECOND JOINT INVENTOR	Seattle, Washington 98103-5913
	Citizen of: United States
ignature of Inventor	Post Office Address: Same as above
Pate	
	830 Watershed
John B. Lowe NAME OF THIRD JOINT INVENTOR	Ann Arbor, Michigan 48105
JAR B Zono	C'. (United States
Signature of Inventor	Citizen of: <u>United States</u> Post Office Address: <u>Same as above</u>
9 May 1996	
NAME OF FOURTH JOINT INVENTOR	_ Residence:
	· · · · · · · · · · · · · · · · · · ·
	Citizen of:
Signature of Inventor	Post Office Address:
Date	
NAME OF FIFTH JOINT INVENTOR	Residence:
Signature of Inventor	Citizen of:
Signature of Inventor	Post Office Address:
Date	

Nower Of Attorney and eclaration.

Page 1 of 3

WE (1) the undersigned inventor(s), hereby declare(s) that:

My residence, post office address and citizenship are as stated below next to my name,

We (I) believe that we are (I am) the original, first, and joint (sole) invertor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled

MURINE $\alpha(1,3)$ FUCOSYLTRANSFERASE FUC-TVII, DNA ENCODING THE SAME, <u>A</u>,

		PREPARING THE SAME,				
		YS FOR DETECTING THE CONTAINING SUCH A PL		MIDS CONTA	INING S	UCH DNA
the specification			ASMID			
the specification	л	i which				
		is attached hereto.				
	X X	was filed on MARCH 8, 1996		as		
		Application Serial No. <u>08/613</u>	,098			
		and amended on		· ·		
		was filed as PCT international app	lication			
Hardy Bridge Service S	Nu	mber				
	on			,		
	and	was amended under PCT Article	19			
) : . (주) 는 국가 :	on		(if ap	pplicable).		
					•	
We (I) her		state that we (I) have reviewe			of the abov	e-identified
specification, i	incl	iding the claims, as amended by an	y amendment reter	red to above.		
We (I) ack		ledge the duty to disclose inform			ne patentabi	lity of this
application as	deti -	ned in Section 1.56 of Title 37 Coo	le of Federal Regula	itions.		
		claim foreign priority benefits u				
		patent or inventor's certificate, one country other than the Unit				
checking the b	ox,	any foreign application for patent	or inventor's certif	ficate, or PCT In	iternational	application
		e before that of the application on				
				•	Prior	ity
Applica	tion	No. Country	Day/N	Month/Year	Clain	ned
					☐ Yes	□ No
					☐ Yes	□ No
					☐ Yes	□ No

Application No.	Country	Day/Month/Year	Claimed	
			☐ Yes	□ No
			□ Yes	□ No
			□ Yes	□ No
			□ Yes	□ No

_			
	(Application Number)	(Filing	Date)
	(Application Number)	(Filing	Date)
PCT International appreach of the claims of the in the manner provide information which is r	plication designating the Unit his application is not disclosed ded by the first paragraph o	ed States, listed below in the prior United Sta of 35 U.S.C. § 112, I fined in 37 CFR § 1.56	ites application(s), or § 365(c) of any and, insofar as the subject matter of tes or PCT International application acknowledge the duty to disclose which became available between the ling date of this application.
Application Seri	al No. Filin	g Date	Status (pending, patented, abandoned)
			
interior in the second			
25,599; Arthur I. Neus D. Hamilton, Registration Number Registration Number Number 31,451; Willia 32,171; Stephen G. B. Robert W. Hahl, Reg. Weihrouch, Registration Number Registration Number Registration Number this application and to	stadt, Registration Number 24 ation Number 28,421; Eckhaumber 29,099; Charles L. Ghar 29,004; William E. Beaus 30,073; Robert F. Gnuse, Regam B. Walker, Registration Number 33,893; Rigon Number 32,829; John T. Gon Number 32,829; John T. Gon Number 34,651; William J. Healey 34,305; our (my) attorneys, we transact all business in the Pate regarding this application between the state of the stat	,854; Richard D. Kelly, and H. Kuesters, Registration Number, Registration Number 27,29 umber 22,498; Timothy 32,884; Martin M. Zochard L. Treanor, Registration, Registration, Registration Number th full powers of substatent Office connected the sent to the firm of Control of the sent to the firm of Control of the States o	ory J. Maier, Registration Number Registration Number 27,757; James tration Number 28,870; Robert T. aber 26,395; Vincent J. Sunderdick, umber 30,996; Steven B. Kelber, 25; Jean-Paul Lavalleye, Registration R. Schwartz, Registration Number 1tick, Registration Number 36,745; istration Number 36,379; Steven P. a Number 26,142; Marc R. Labgold, 27, 36,160; and Richard L. Chinn, itution and revocation, to prosecute therewith; and we (I) hereby request 19, 100, 100, 100, 100, 100, 100, 100,
MAIER & NEUSTAL Arlington, Virginia 22 We (I) declare that made on information knowledge that willfu under Section 1001 of the validity of the app	202. all statements made herein o and belief are believed to be 1 false statements and the like	f our (my) own knowl true; and further that t so made are punishabl Code and that such wi thereon.	oor, 1755 Jefferson Davis Highway, edge are true and that all statements hese statements were made with the e by fine or imprisonment, or both, llful false statements may jeopardize
MAIER & NEUSTAL Arlington, Virginia 22 We (I) declare that made on information knowledge that willfu under Section 1001 of	all statements made herein o and belief are believed to be I false statements and the like Title 18 of the United States lication or any patent issuing	f our (my) own knowl true; and further that t so made are punishabl Code and that such wi thereon.	oor, 1755 Jefferson Davis Highway, edge are true and that all statements hese statements were made with the e by fine or imprisonment, or both
MAIER & NEUSTAL Arlington, Virginia 22 We (I) declare that made on information knowledge that willfu under Section 1001 of the validity of the app Shunji NATSUKA	all statements made herein o and belief are believed to be I false statements and the like Title 18 of the United States lication or any patent issuing	f our (my) own knowl true; and further that to so made are punishable Code and that such withereon. Residence: 142 Citizen of: JA	edge are true and that all statements hese statements were made with the by fine or imprisonment, or both allful false statements may jeopardized. 3 Natalie Lane, #79

Kevin M. GERSTEN	Residence: 1826 N. 7th Street
NAME OF SECOND JOINT INVENTOR	Seattle, Washington 98103-5913
Kerin M. Serota	Citizen of:United States
Signature of Inventor	Post Office Address: _Same as above
6/18/96	
Date	
John B. Lowe	Residence: 2472 Antietam Drive
NAME OF THIRD JOINT INVENTOR	Ann Arbor, Michigan 48105
	Citizen of: United States
Signature of Inventor	Post Office Address: Same as above
f= 21	· · · · · · · · · · · · · · · · · · ·
	Residence:
NAME OF FOURTH JOINT INVENTOR	
	Citizen of:
Signature of Inventor	Post Office Address:
-	
Date	
· .	Residence:
NAME OF FIFTH JOINT INVENTOR	
	Citizen of:
Signature of Inventor	Post Office Address:

Date

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

SHUNJI NATSUKA ET AL

: EXAMINER: NOLAN

SERIAL NO. 08/613,098

FILED: MARCH 8, 1996

: GROUP ART UNIT: 1644

FOR: MURINE ALPHA (1,3)

FUCOSYLTRANSFERASE FUC-TVIL

DNA ENCODING THE SAME,
METHOD FOR PREPARING THE
SAME, ANTIBODIES RECOGNIZING
THE SAME, IMMUNOASSAYS FOR
DETECTING THE SAME, PLASMIDS
CONTAINING SUCH DNA, AND CELLS

CONTAINING SUCH A PLASMID

DECLARATION UNDER 37 C.F.R. 81.132

ASSISTANT COMMIS	SIONER FOR PATENTS
WASHINGTON, D.C.	20231

SIR:

Now comes John B. Lowe who deposes and states:

- 1. That I am a named inventor of U. S. Patent Application Serial No. 08/613,098.
- 2. That I am Professor of Pathology, University of Michigan Medical School and Investigator, Howard Hughes Medical Institute.
- That I am a graduate of University of Utah College of Medicine and received my
 M.D. in the year 1980,
- 4. That I have been employed by the University of Michigan for 11 years as a Professor of Pathology.

ď)

in Hand

= 6

jì [2]

=35

- 5. That a copy of my curriculum vitae is attached hereto and is incorporated into and is part of this Declaration.
- 6. That I have been engaged in research involving the cloning of glycosyltransferase genes, including both human and murine fucosyltransferases, for 12 years.
- 7. That, based on my experience in the field of glycosyltransferase research, it is my understanding that the person having ordinary skill in the art of glycosyltransferase research would typically have a Ph.D. or M.D. and 5 years of postdoctoral or research experience in biochemistry or molecular biology.
- 8. That it is my opinion that the combined teachings of K. Sasaki et al. "Expression Cloning of a Novel al.3-Fucosyltransferase That Is Involved in Biosynthesis of the Sialyl Lewis x Carbohydrate Determinants in Lcukocytes," The Journal of Biological Chemistry, vol. 269, pp. 14730-14737 (1994) (<u>Sasaki et al</u>) and K. Gersten, "Structure, Function, and Tissue-Specific Expression Patterns of Murine α(1-3)Fucosyltransferase Genes," The Journal of Cellular Biochemistry, Supplement 16D, p. 170, Abstract No. P 407 (1992), would not have instilled in the person having ordinary skill in the art of glycosyltransferase research, at the time U.S. Patent Application Serial No. 08/613,098 was filed (March 8, 1996), a reasonable expectation of success for the existence of a murine analogue to human Fuc-TVII.
- 9. That my opinion is based, in part, on the experiences of the researchers working in my own laboratory. The genes encoding human Fuc-TIII. Fuc-TV, and Fuc-TVI, were isolated in my laboratory in 1988, 1990, and 1991, respectively. For 5 years, researchers in my laboratory have attempted to clone the genes encoding the murine counterparts of Fuc-TIII, Fuc-TV, and Fuc-TVI. The efforts spent in attempting to clone the genes encoding the murine counterparts of Fuc-TIII, Fuc-TV, and Fuc-TVI have been extensive and have included:

ᆄ



- (A) Mammalian expression cloning (using an approach virtually identical to that described in Kukowska-Latallo et al, Genes and Development, vol. 4, pp. 1288-1303 (1990));
- (B) Cross-hybridization approaches using bacteriophage libraries containing mouse genomic DNA (as described in Weston et al, The Journal of Biological Chemistry, vol. 267, pp. 4152-4169 (1992) and Weston et al, The Journal of Biological Chemistry, vol. 267, pp. 24575-24584 (1992));
- (C) The polymerase chain reaction and degenerate PCR primers designed to correspond to most highly conserved portions of all known mammalian α(1.3)fucosyltransferases; and
- (D) Chromosome walking techniques. In this approach, a large number of cloned segments of the mouse chromosome that corresponds to the part of human chromosome 19 where the genes for Fuc-TIII, Fuc-TTV, and Fuc-TVI are located. This segment was then exhaustively screened for the presence of Fuc-TIII, Fuc-TTV, and Fuc-TVI homologues, also using the PCR and hybridization approaches used above. Only one fucosyltransferase-cross-hybridizing DNA sequence was identified in this large segment of the mouse chromosome and it turned out to be the mouse pseudogene that had been cloned some years ago.

Thus, even though human Fuc-TIII, Fuc-TIV, and Fuc-TVI are known, no mouse analogues are known. Thus, the disclosure of human Fuc-TVII in Sasaki et al would not have instilled an expectation of the existence of murine Fuc-TVII.

10. That my opinion is, in part, based on the experiences of other researchers. Other researchers have found that there exists only a single bovine fucosyltransferase gene which corresponds to the human genes for Fuc-TIII, Fuc-TV, and Fuc-TVI (see: A. Oulmouden et al, The Journal of Biological Chemistry, vol. 272, pp. 8764-8773 (1997)). Some of the same researchers have concluded that the human genes for Fuc-TIII, Fuc-TV, and Fuc-TVI arose as

1400

a result of gene duplication between: (i) the great mammalian radiation 80 million years ago and (ii) the separation of man and chimpanzes 10 million years ago (see: M. Costache et al., The Journal of Biological Chemistry, vol. 272, pp. 29721-29728 (1997)). Since the mouse can be placed much "earlier" on the "evolutionary tree," it is logical to conclude that the mouse does not have functional versions of Fuc-TIII, Fuc-TV, and Fuc-TVI. It is also logical to conclude that the skilled artisan would not have a reasonable expectation of success for the existence of a murine analogue based on the mere disclosure of a particular human fucosyltransferase.

- 11. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.
 - 12. Further deponent saith not.

gnature

Date